REMARKS

Claims 4, 5, 7, 9-19, 24, 27, 28, 30, 33, and 36-62 are pending in the application. Claims 4, 5, 7, 9-19, 24, 27, 28, 30, 33, and 36-62 are rejected. Claims 7 and 18 are presently cancelled. Claims 4, 17, 19, 33, 36, 37, and 62 are presently amended. In view of the claim amendments and the discussion below, Applicant submits that the application is now in condition for allowance.

Claim Rejections 35 U.S.C. § 112

The Examiner has rejected claim 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has presently cancelled claim 7. Applicant therefore submits that the rejection of claim 7 has been rendered moot, and respectfully requests a withdrawal of the rejection of claim 7 under 35 U.S.C. § 112, second paragraph.

The Examiner has rejected claim 19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner states that the recitation of "said composition" in claim 19 renders the claim indefinite because the particular "composition" being referred to is unclear. In response, Applicant has presently deleted "in said composition" from claim 19. Applicant therefore

respectfully requests a withdrawal of the rejection of claim 19 under 35 U.S.C. § 112, second paragraph.

The Examiner has rejected claim 36 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner suggests that claim 33 (from which claim 36 depends) recites that the "first ingredient includes a coumarin" whereas claim 36 recites that "the first ingredient is Cnidium monnier," and so the two limitations are at odds with one another, and thus lack clarity. Applicants respectfully disagree. Applicants submit that, as described throughout the specification, Cnidium monnier includes coumarins. Thus, Cnidium monnier *is* a first ingredient including a coumarin. Thus, the two limitations are not at odds with one another. However, to further clarify this point in order to expedite prosecution, Applicant has presently amended claim 36 to recite that the "first ingredient including a coumarin is Cnidium monnier." Applicant therefore respectfully requests a withdrawal of the rejection of claim 36 under 35 U.S.C. § 112, second paragraph.

The Examiner has rejected claim 17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, Claim 17 is drawn to a pharmaceutical composition including a first ingredient being Eurycoma longifolia Jack, a second ingredient effective to stimulate the production of cGMP, and a third ingredient in homeopathic form for stimulating an increase in blood

flow. The Examiner suggests that the scope of the claim includes numerous third ingredients that may be effective to stimulate an increase in blood flow, and, as such, the claim recites a genus that is so highly variable that it is too broad to show that the Applicant had possession of the claimed invention at the time of the application.

In response, Applicant has amended claim 17 to recite that the third ingredient is Epimedium sagittatum. Support for this amendment may be found at least at page 9, lines 9-12; page 20, line 5 through page 21, line 5; and originally filed claim 18. In view of the amendment, Applicant respectfully requests a withdrawal of the rejection of claim 17 under 35 U.S.C. § 112, first paragraph.

Claim Rejections 35 U.S.C. § 103

Garfield/Ang/Chwalisz/Coral-Cure/Chen/Chiou

The Examiner has maintained the rejection of claims 4, 5, 7-19, 22, 24, 27, 28, 30, 33, and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,595,970 (Garfield) taken with Ang et al. Arch Pharm Res. 2001, 24(5):437-40, 2001, Abstract (Ang) and U.S. Patent No. 5,906,987 (Chwalisz), and Coral-Cure, www.coral-cure.com/mens-health (Coral-Cure) in view of Chen et al. Exp. Opin. Ther. Patents (Chen), Bulk Nutrition 1, 2002 (Bulk Nutrition), and Chiou et al. Planta Med. 2001 67:282-284 (Chiou). Applicant respectfully disagrees.

As an initial matter, Applicant notes that claims 7 and 18 have been presently cancelled, thereby rendering moot the rejection of claims 7 and 18 under 35

U.S.C. § 103(a) as patentable over Garfield taken with Ang, Chwalisz, and Coral-Cure, in view of Chen, Bulk Nutrition, and Chiou.

The remaining claims rejected by the Examiner as obvious over Garfield taken with Ang, Chwalisz, and Coral-Cure, in view of Chen, Bulk Nutrition, and Chiou include independent claims 4 and 33 (claims 5, 8-17, 19, 22, 24, 27, 28, 30, and 36 are ultimately dependent on either claim 4 or claim 33).

Regarding independent claim 4, the Examiner states that Garfield teaches a second ingredient to stimulate the production of cyclic GMP, but does not teach Eurycoma Longifolia Jack. However, the Examiner states that Ang teaches that Eurycoma Longifolia Jack "has gained notoriety of a symbol of a man's ego when administered." Thus, the Examiner suggests that a person of ordinary skill in the art would be motivated to add the natural herb (i.e., Eurycoma Longifolia Jack) taught by Ang to the composition of Garfield, since Eurycoma Longifolia Jack has the same function as testosterone.

Regarding independent claim 33, the Examiner states that Chiou teaches the vasorelaxing effects of coumarins from Cnidium monnier. Chiou does not teach a vesicle operable for transporting the first ingredient including a coumarin. However, the Examiner states that Chen teaches the use of phosphatidyl choline as a vesicle carrier. The Examiner therefore suggests that a person of ordinary skill in the art would be motivated to deliver the Cnidium monnier of Chiou via the vesicle of Chen because

phosphatidyl choline is a major component of cellular membranes, and functions in the transport of lipoproteins into tissues. Applicant respectfully disagrees with the rejection of independent claims 4 and 33 (and thus their dependent claims).

As an initial matter, Applicant notes that independent claims 4 and 33 have each been amended to recite that "the composition is in a form adapted to be administered topically, the form being chosen from a moisturizer, a cream, a lotion, a gel, an ointment, and an emulsion." Support for this amendment may be found at least at page 14, line 1, of the present application. And, independent claims 4 and 33 each also recite a "coumarin" as a component of the composition that is administered topically in the form of a moisturizer, cream, lotion, gel, ointment, or emulsion.

In response to previous Office Actions, Applicant had argued that no reference, or combination of references, cited by the Examiner taught or suggest a coumarin being delivered transdermally. In the present Office Action, the Examiner does not argue that the previously cited references teach or suggest transdermal delivery of a coumarin. Rather, in the present Office Action, the Examiner newly cites PCT Publication No. WO 2000/012582 (Cilurzo), and states that Cilurzo shows coumarins being administered transdermally.

Cilurzo particularly describes a transdermal plaster, which may contain a coumarin, and includes an adhesive layer that allows it to be adhered to the skin of a subject. Thus, Cilurzo describes a plaster, rather than any cream, moisturizer, lotion,

etc. (as recited in independent claims 4 and 33). In fact, Cilurzo describes that this plaster and adhesive was developed because of the many drawbacks found in topical applications, such as creams. In particular, at page 3, line 25 through page 4, line 4, Cilurzo states:

> "... it is necessary to apply coumarin topically in the form of cream over a wide area of the body, and in any case, as acknowledged by the authors of the above study, even applying it over an area of 30 cm^2, absolute bioavailability reaches only 66% of the total. In addition, transdermal absorption using cream presents a series of drawbacks, such as lack of reproducibility, in particular an account of the poor control over the amount of cream on the surface of the skin on which it is spread. It should also be added that it is not always pleasant for the person affected by chronic venous insufficiency to apply a cream that leaves visible residue on the skin in the area of application, which, in this case, as was noted above, must be very extensive for satisfactory results to be achieved."

Cilurzo, then, is explicit that administration forms such as creams are not to be used to deliver coumarin, due to the many drawbacks associated with doing so. It is only the work of Applicant, as described in the present specification and recited in the claims of the present application that, for the first time, teaches topical creams, lotions, etc. that are used to deliver a coumarin transdermally (as well as other ingredients). Thus, not only does Cilurzo not teach any topical cream, moisturizer, lotion, etc., Cilurzo clearly teaches away from the use of topical forms, such as creams, and thus teaches away from the invention as recited in presently pending independent claims 4 and 33

(both of which recite a topical form, such as moisturizers, creams, lotions, gels, ointments, and emulsions).

In view of the above, Applicant respectfully requests a withdrawal of the rejection of independent claims 4 and 33 as obvious over Garfield taken with Ang, Chwalisz, and Coral-Cure in view of Chen, Bulk Nutrition, and Chiou, and also in view of Cilurzo under 35 U.S.C. § 103. As independent claims 4 and 33 are nonobvious, Applicant further requests a withdrawal of the rejection of dependent claims 5, 8-17, 19, 22, 24, 27, 28, 30, and 36 (as each of those claims ultimately depends from independent claim 4 or independent claim 33) as obvious under 35 U.S.C. § 103.

Garfield/Ang/Chwalisz/Coral-Cure/Chen/Bulk Nutrition/Chiou/Mesko/McKoy

The Examiner has also maintained the rejection of claims 37-60, and has newly rejected claims 61 and 62, as obvious over Garfield taken with Ang, Chwalisz, and Coral-Cure, in view of Chen, Bulk Nutrition, and Chiou in further view of U.S. Patent No. 6,340,474 (Mesko) and McKoy et al. Proc. West. Pharmacol. Soc., 45:76-78 2002 (McKoy). The Examiner previously pointed to Garfield as teaching a hormone, and points to McKoy as teaching that Morinda citrifolia is used to treat sexual dysfunction. The Examiner then states that since it is known in the art that Morinda citrifolia is used to treat sexual dysfunction, one of ordinary skill in the art would add that ingredient (presumably to the composition of Garfield – though the Examiner never specifically

states that) to enhance the overall activity of the composition when administered for the same treatment. Applicant respectfully disagrees.

Presently amended independent claim 37 (from which each of claims 38-61 ultimately depend) recites a composition comprising (1) "a first ingredient chosen from a hormone, a composition which potentiates a hormone, and mixtures thereof," (2) "a second ingredient chosen from Morinda citrifolia and an extract of Morinda citrifolia," and (3) "a third ingredient being a coumarin," wherein "the composition is in a form adapted to be administered topically, the form being chosen from a moisturizer, a cream, a lotion, a gel, an ointment, and an emulsion."

Further, presently amended independent claim 62 recites a composition comprising (1) a first ingredient being Eurycoma longifolia jack; (2) a second ingredient effective to stimulate the production of cyclic GMP, wherein the second ingredient inhibits the activity of at least one enzyme, the enzyme being a phosphodiesterase; and (3) "a third ingredient being a coumarin," wherein "the composition is in a form adapted to be administered topically, the form being chosen from a moisturizer, a cream, a lotion, a gel, an ointment, and an emulsion."

As independent claims 37 and 62 now each recite a "coumarin" and "the composition [being] in a form adapted to be administered topically, the form being chosen from a moisturizer, a cream, a lotion, a gel, an ointment, and an emulsion," Applicant submits that those claims are nonobvious over the cited references. None of

the references specifically cited by the Examiner with respect to the rejection of independent claims 37 and 62 teach or suggest the transdermal delivery of a coumarin via a topically applied form such as a cream, lotion, ointment, etc. Rather, as described above with respect to the rejection of independent claims 4 and 33, the only reference cited by the Examiner for transdermal delivery of a coumarin is Cilurzo. However, Cilurzo particularly describes a transdermal plaster, which may contain a coumarin, and includes an adhesive layer that allows it to be adhered to the skin of a subject. Thus, Cilurzo does not describe any cream, moisturizer, lotion, etc. (as recited in independent claims 37 and 62). In fact, Cilurzo describes that this plaster and adhesive was developed because of the many drawbacks found in topical applications, such as creams. In particular, at page 3, line 25 through page 4, line 4, Cilurzo states:

> "... it is necessary to apply coumarin topically in the form of cream over a wide area of the body, and in any case, as acknowledged by the authors of the above study, even applying it over an area of 30 cm^2, absolute bioavailability reaches only 66% of the total. In addition, transdermal absorption using cream presents a series of drawbacks, such as lack of reproducibility, in particular an account of the poor control over the amount of cream on the surface of the skin on which it is spread. It should also be added that it is not always pleasant for the person affected by chronic venous insufficiency to apply a cream that leaves visible residue on the skin in the area of application, which, in this case, as was noted above, must be very extensive for satisfactory results to be achieved."

Cilurzo, then, is explicit that administration forms such as creams are not to be used to deliver coumarin, due to the many drawbacks associated with doing so. It is only the work of Applicant, as described in the present specification and recited in the claims of the present application that, for the first time, teaches topical creams, lotions, etc. that are used to deliver a coumarin transdermally (as well as other ingredients). Thus, not only does Cilurzo not teach any topical cream, moisturizer, lotion, etc., Cilurzo clearly teaches away from the use of topical forms, such as creams, and thus teaches away from the invention as recited in presently pending independent claims 37 and 62 (both of which recite a topical form, such as moisturizers, creams, lotions, gels, ointments, and emulsions).

In view of the above, Applicant respectfully requests a withdrawal of the rejection of independent claims 37 and 62 as obvious under 35 U.S.C. § 103(b). As independent claims 37 and 62 are nonobvious, Applicant further requests the withdrawal of the rejection of dependent claims 38-61 (as each of those claims ultimately depends from independent claim 37) as obvious under 35 U.S.C. § 103(b).

Conclusion

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

The fee for a Request for Continued Examination is being submitted on even date herewith. Please consider this paper a Petition for an Extension of Time of three months. A fee of $555.00 is believed due as a result of this Petition. No other fee is believed due. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,
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